Annals of Clinical and Analytical Medicine
Original Research

Evaluation of clinical features and treatment responses in cardiac and vascular involvement of Behçet's disease

Clinic and treatment responses in vascular Behçet's disease

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Abstract
Aim: Cardiovascular system (CVS) involvement stands as a significant contributor to morbidity and mortality in Behçet's disease. We aimed to evaluate the clinical features and treatment responses in cardiac and vascular involvement of Behçet's disease.
Material and Methods: This study was conducted as a single-center, retrospective clinical trial, focused on Behçet's patients with CVS involvement, analyzing patterns of CVS involvement, treatment modalities, and vascular relapse development.
Results: Among the 271 Behçet's patients examined, 61 with CVS involvement meeting the study criteria were included. The median age at the first vascular attack was 31 years (range: 20-62), with 83.7% male ($p<0.001$). Venous involvement was in 49 patients (80.3%). Throughout the follow-up period, vascular relapse was observed in 36.4% (8/22) of patients under immunosuppressive (IS) treatment alone, 90.9% (10/11) under anticoagulant (AC) treatment alone, and 48% (12/25) under combined (IS+AC) treatment ($p=0.025$).
Discussion: Our findings suggest that the addition of anticoagulant therapy to the treatment regimen of Behçet's disease patients with CVS involvement does not mitigate the risk of vascular relapse. However, the need for larger-scale studies on this subject is obvious.

Keywords
Behçet's Disease, Cardiovascular Involvement, Treatment, Vascular Relapse, Anticoagulant Therapy

DOI: 10.4328/ACAM.22198 Received: 2024-03-26 Accepted: 2024-05-13 Published Online: 2024-07-02 Printed: 2024-08-01 Ann Clin Anal Med 2024;15(8):575-580
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This study was approved by the Ethics Committee of Karadeniz Technical University, Faculty of Medicine (Date: 2020-01-31, No: 24237859-99)

Introduction

Behçet's disease (BD) manifests with a spectrum of systemic symptoms, encompassing recurrent oral aphthae, genital ulcers, eye manifestations, skin lesions, arthritis, gastrointestinal, neurological, cardiac, and vascular involvement [1]. Notably, cardiovascular system (CVS) involvement emerges as a significant contributor to morbidity and mortality in BD. This disease is noteworthy for its propensity to affect blood vessels of all calibers, encompassing small, medium, and large vessels, both arterial and venous [2, 3]. Furthermore, a diverse array of clinical presentations may arise from various forms of cardiac involvement [4-6].

The 2018 EULAR guideline provides guidence on the treatment of Behçet's disease (BD), particularly in cardiovascular involvement cases. Therapy typically involves immunosuppressive agents alongside high-dose glucocorticoids, with azathioprine or cyclophosphamide commonly used [7]. Monoclonal anti-TNF agents like infliximab and adalimumab show promise in managing recurrent venous thrombosis [8-12]. While combining anticoagulant therapy with immunosuppressants doesn't reduce vascular relapse risk, reduced protein C and Protein S levels may indicate anticoagulant use [4, 13, 14]. Therefore, adjunctive anticoagulant therapy may be considered, especially for recurrent venous thrombosis cases, after ruling out pulmonary artery aneurysm and assessing bleeding risk [7].

Given its significant morbidity and mortality rates, the management of CVS involvement in BD has been extensively explored in the literature and remains an area of ongoing investigation. This study aimed to evaluate the clinical features and treatment responses in CVS involvement of Behçet's disease.

Material and Methods

Study design

This study was conducted as a single-center, retrospective clinical study following the principles of the Declaration of Helsinki.

Study population

Adults (≥18 years old) diagnosed with BD according to ISG criteria and treated at a tertiary hospital from January 2009 to January 2020 were included. The criteria required complete blood count and blood biochemistry test results, with accessible medical records. Exclusions comprised patients with other inflammatory diseases, malignancy, infection, ulcerative colitis, Familial Mediterranean Fever (FMF), Systemic Lupus Erythematosus (SLE), and those without CVS involvement.

Vascular involvement included venous thrombus, arterial thrombus, and/or arterial aneurysm. Cardiac involvement comprised pericarditis, myocarditis, intracardiac thrombus, and/or myocardial infarction. Confirmation necessitated pathological findings via clinical examination and imaging modalities like Doppler ultrasonography, computed tomographic angiography, magnetic resonance angiography, interventional arteriography/venography, and echocardiography. A vascular attack (relapse) denoted the emergence of a new thrombus/aneurysm or enlargement of an existing one.

Data collection

The hospital's automated system captured data on sociodemographic factors, clinical profiles, laboratory results, prescribed medications, details of CVS involvement, and imaging outcomes. Any missing data specified in the study protocol were gathered through interviews with patients either by phone or in person. Throughout the follow-up period, information such as the onset of CVS involvement, treatments administered post-CVS involvement, treatment duration, occurrence of new vascular attacks during treatment, and time until new vascular attacks (vascular relapse) were noted. Medical interventions during and after attacks were categorized into anticoagulant (AC), corticosteroid (CS), and immunosuppressive (IS) treatments, adhering to the guidelines outlined by the European League Against Rheumatism (EULAR) [7].

Outcome measure(s)

The primary endpoint of this study is to evaluate the clinical features and treatment responses in cardiac and vascular involvement of Behçet's disease. The secondary endpoint is to determine the effect of vascular involvement on the mortality of BD.

Statistical method(s)

Data analysis was conducted using IBM SPSS Statistics 25. Descriptive statistics were reported as numbers (n) and percentages (%) for categorical variables. Normality was assessed using the Kolmogorov-Smirnov test. Normally distributed numerical variables were presented as mean ± standard deviation, while non-normally distributed variables were expressed as median (minimum-maximum). For comparisons between groups, the Student's t-test and Mann Whitney U test were used for normally and non-normally distributed variables, respectively. Categorical variables were compared using the chi-square test. Kaplan-Meier analysis assessed cumulative and relapse-free survival, with log-rank testing for comparisons based on arterial/vascular involvement. A significance level of $p<0.05$ was considered statistically significant.

Ethical Approval

This study was approved by the Ethics Committee of Karadeniz Technical University Faculty of Medicine (Date: 2020-01-31, No: 24237859-99).

Results

Data from 271 Behçet's disease patients were gathered during the specified period, with 61 patients exhibiting CVS involvement included in the study. The median age of patients with CVS involvement at BD diagnosis was 28 years (10-58 range). At the onset of the first vascular attack, the median age was 31 years (20-62 range). Gender analysis showed that 83.7% (n=51) were male and 16.3% (n=10) were female ($p<0.001$). The median follow-up duration was 42 months (0-182 range).

The distribution of CVS involvement types and anatomical localization was analyzed (Table 1). Among the 61 patients, 49 (80.3%) had venous involvement, 21 (34.4%) had arterial involvement, and 9 (14.8%) had both venous and arterial involvement. Additionally, cardiac involvement was noted in 2 patients (3.2%), both with intracardiac thrombus formation.

At Behçet's disease diagnosis, 50.8% (31/61) had CVS involvement, while 48.2% (30/61) developed it later, with a

mean diagnosis time of 61.23±50.96 months. Among those affected, 52.5% (32/61) had a first vascular relapse, 22.9% (14/61) a second, and 8.2% (5/61) a third. (Figure 1). Initially, 6.5% (4/61) received IS for other organ issues, while 54.1% (33/61) were medication-free. Later, 77% (47/61) received IS treatment. Azathioprine (68.8%, 42/61), colchicine (83.6%, 51/61), and steroids (42.6%, 26/61) were common treatments, with smaller percentages using cyclophosphamide, pulse steroids, cyclosporine, interferon, and adalimumab.

No AC treatment was administered during the initial vascular attack. After the first vascular event, 59% (n=36) of patients started AC therapy, with 40.9% (n=25) receiving combined IS and AC treatment concurrently. The incidence of new vascular attacks varied across groups: 36.4% (8/22) with IS treatment alone, 90.9% (10/11) with AC treatment alone, and 48% (12/25) with IS+AC combined treatment (p=0.025). Patients receiving IS treatment alone had fewer vascular attacks than those on AC alone (p=0.009), but the relapse incidence did not significantly differ between IS treatment alone and IS+AC combined treatment (p=0.061) (Table 2). See the graphical abstract (Figure 2) for a summary.

The median duration of IS usage between the first and second vascular attacks was 23 months (range: 2-104), while the median period of AC usage during this interval was 7 months (range: 1-60). There was no significant difference in IS and AC

Table 1. Demographic and Clinical Characteristics of the Patients in the Study

Feature	n (%)
Gender	
-Male	51 (83.7)
-Woman	10 (16.3)
Oral aphthae	61 (100)
Genital ulcer	52 (85.2)
Papulopustular eruption	25 (41)
Erythema nodosum	29 (47.5)
Eye involvement	23 (37.7)
Neurological involvement	6 (9.8)
Gastrointestinal tract involvement	2 (3.3)
Joint involvement	14 (23)
Genitourinary involvement	6 (9.8)
Lung parenchymal involvement	3 (4.9)
Cardiovascular system involvement	61 (100)
Venous involvement	49 (80.3)
Lower extremity DVT: Deep Venous Thrombosis	39 (63,9)
One-sided	25 (41)
Bilateral	14 (23)
Iliac vein	6 (9,8)
Femoral vein	25 (41)
Popliteal vein	29 (47.5)
Superficial Thrombophlebitis	22 (36.1)
Upper Extremity DVT	2 (3.3)
Cranial Sinus Thrombosis	4 (6.6)
Vena Cava Superior Thrombosis	4 (6.6)
Brachiocephalic Vein Thrombosis	3 (4.9)
Vena Cava Inferior Thrombosis	1 (1.6)
Arterial involvement	21 (34.4)
Pulmonary Artery Aneurysm	8 (13.1)
Pulmonary Artery Thrombus	10 (16.4)
Abdominal Aortic Aneurysm	3 (4.9)
Abdominal Aortic Thrombus	1 (1.6)
Anterior Communican a. Aneurysm	2 (3.3)
Femoral Artery Aneurysm	1 (1.6)
Celiac Truncus Aneurysm	1 (1.6)
Cardiac involvement	2 (3.2)
Intracardiac thrombus	2 (3.2)

Table 2. Comparison of Vascular Relapse Developments According to Treatments Given

Type of Treatment	Vascular Relapse		p
	Yes n (%)	None n (%)	
IS[a,b]	8 (36.4)	14 (63.6)	
AC[a]	10 (90.9)	1 (9.1)	0.025
(IS+AC)[b]	12 (48)	13 (52)	

a: p=0.009; b: p=0.61; IS: Immunosuppressive, AC: Anticoagulant

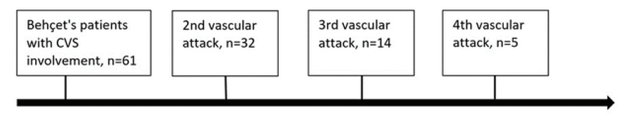

Figure 1. Development of vascular attacks over time in Behçet's patients with cardiovascular involvement

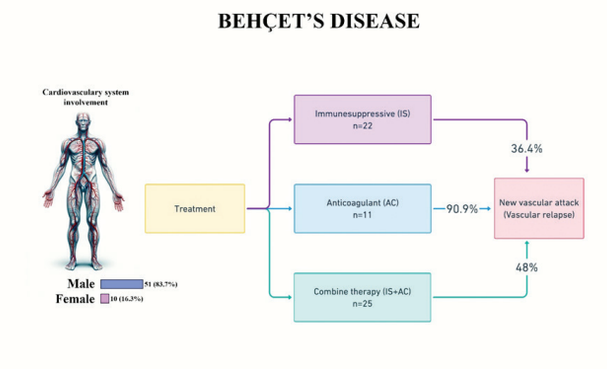

Figure 2. Graphical Abstract of the Study

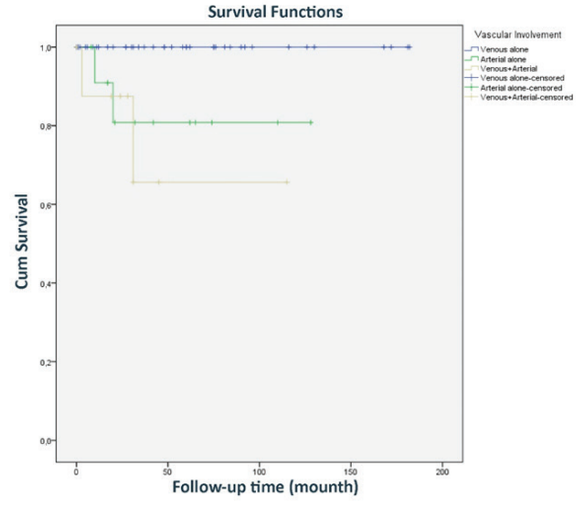

Figure 3. Cumulative Survival Curve According to Vascular Involvement Types

usage duration between patients with and without a second vascular attack (first vascular relapse) (p=0.302 and p=0.864, respectively). The mean interval between the first and second vascular attacks was 41.8±39.6 months. At the time of the second vascular attack, 21.8% (7/32) were on IS treatment, and 18.7% (6/32) were receiving AC treatment. Among the 32 patients with a second vascular episode, one died from pulmonary artery aneurysm bleeding and one from abdominal aortic aneurysm bleeding without treatment.

The mean interval between the second and third vascular attacks was 36.14±30.9 months. At the onset of the third vascular attack, 7.1% received IS treatment, and 21.4% were on AC treatment. None received IS+AC combination therapy. Among those with a third attack, one died before treatment, bleeding from an abdominal aortic aneurysm.

The mean interval between the third and fourth vascular attacks was 25.8±10.8 months. One of five patients with a fourth attack died from a pulmonary artery aneurysm hemorrhage.

Adverse drug reactions in the 61 patients were examined. Among 56 starting azathioprine, two halted due to severe dyspepsia and three due to liver enzyme elevation. Four began infliximab, but one ceased due to an allergic infusion reaction. Additionally, anticoagulant complications included retinal hemorrhage, massive hematuria, and hemothorax in separate cases.

Interventional procedures performed on the patients were also analyzed. Two patients underwent thrombectomy for lower extremity thrombosis, while one underwent surgery for an abdominal aortic aneurysm but died from bleeding due to an aorta-enteric fistula. Another patient received stenting for an abdominal aortic aneurysm, and one died during surgical intervention for abdominal aortic aneurysm rupture.

Survival analysis for patients stratified by types of vascular involvement was conducted. Cumulative survival curves by vascular involvement types (Figure 3) were presented. The two-year relapse-free survival rate was 71.1%, decreasing to 45.7% at five years. The impact of vascular involvement types (venous only, arterial only, venous+arterial) on relapse-free survival showed no significant difference (p=0.297). However, analyzing vascular involvement patterns on cumulative survival indicated an earlier breakthrough in venous+arterial involvement compared to arterial involvement alone (p=0.014), with no mortality observed in patients with venous involvement only.

During the follow-up period, 4 (6.5%) out of 61 patients with CVS involvement died, with a significantly higher mortality rate noted in patients with arterial involvement compared to those without (p=0.011).

Discussion

While cardiovascular system (CVS) involvement holds considerable clinical significance in Behçet's Disease (BD), it has yet to be formally integrated into diagnostic criteria. Our thorough examination of treatment modalities among BD patients with CVS involvement revealed a predominant presentation of venous or arterial thrombosis. Immunosuppressive therapy emerged as the cornerstone in managing these manifestations. Intriguingly, the adjunctive use of anticoagulants, either alone or in combination with immunosuppressive therapy, did not exhibit a discernible protective effect against the occurrence of vascular attacks.

In BD, cardiovascular system involvement holds significant clinical implications, often associated with increased mortality and morbidity [3]. However, data regarding the prevalence of CVS involvement exhibit considerable variability. In our study, CVS involvement was identified in 61 out of 271 Behçet's patients, accounting for 22.5% of the cohort. Contrasting this, a study conducted in China reported a vascular involvement rate of 18.9%, while another study in Turkey, comprising 2319 patients, found a rate of 14.3% [15-16]. These discrepancies in prevalence rates may be attributed to various factors, including differences in ethnic backgrounds and sample sizes across studies. Furthermore, it is noteworthy that CVS involvement tends to be more prevalent among male individuals [17]. Indeed, our study similarly observed a predominance of male patients among those with CVS involvement during the follow-up period. Consequently, it is imperative to routinely inquire about suggestive symptoms of CVS involvement in male patients during clinical visits.

In a study by Alibaz et al. involving 260 Behçet patients with CVS involvement, they found that 84.6% had venous involvement, 8.1% had arterial involvement, 4.2% had both venous and arterial involvement, and 3.1% had cardiac involvement [18]. Similarly, our study showed venous involvement predominance (80.3%). However, our rates of exclusive arterial involvement (19.6%) and venous+arterial involvement (14.8%) were slightly higher than in Alibaz et al.'s study, while cardiac involvement (3.2%) remained similar. Conversely, Fei et al.'s survey of 102 patients reported venous involvement at 70.6% and arterial involvement at 54.9% in Behçet's patients with CVS involvement [19]. These differences may stem from variations in sample sizes and patient demographics, including ethnic diversity among study populations.

Fei et al. found that deep vein thrombosis was the primary venous manifestation, accounting for 68% of cases, while aortic involvement predominated among arterial cases, representing 34% [19]. In contrast, previous studies highlighted superficial thrombophlebitis as the most common venous form [16]. However, our analysis revealed deep vein thrombosis of the lower extremities as the leading venous manifestation, accounting for 63.9% of cases. Notably, pulmonary artery involvement (thrombosis and aneurysm) emerged as the primary arterial involvement, constituting 66.6% of cases, contrasting with previous findings. This aligns with Sarıca et al.'s study, where pulmonary artery involvement ranked highest among arterial involvement types, representing 54.1% of cases [16].

Alibaz et al. found that 57.3% of patients with cardiovascular system (CVS) involvement had vascular manifestations upon Behçet's disease diagnosis [18]. In our study, this rate was slightly lower at 50.8% (31/61). While Alibaz et al. reported lower rates of second, third, and fourth vascular attacks (33%, 6.5%, and 1%, respectively), we observed higher rates (52.5%, 22.9%, and 8.2%, respectively). This difference may be due to patient adherence to immunosuppressive therapies and a higher proportion of arterial involvement in our cohort. We suggest adjusting medication doses or considering alternative

immunosuppressive regimens for patients experiencing recurrent vascular attacks in Behçet's disease with CVS involvement.

In a 2014 retrospective study, 35.4% of Behçet's patients with vascular involvement experienced new vascular attacks during follow-up, with rates of 23% within two years and 38.4% within five years [20]. Our study observed a higher incidence, with 49.2% of patients experiencing at least one new vascular attack during follow-up, likely due to our longer observation period.

Cardiovascular involvement significantly impacts mortality and morbidity in Behçet's disease [3]. Our study found a mortality rate of 6.5% (4/61) among patients with CVS involvement, contrasting with no deaths among those without CVS involvement (0/210) (p=0.002). All fatalities occurred in patients with arterial involvement, emphasizing its role in mortality prediction. Early screening for arterial involvement sites may facilitate prompt initiation of immunosuppressive therapy.

Currently, there are no definitive guidelines supported by randomized controlled trials for treating Behçet's disease (BD) with vascular involvement. Vascular pathology in BD stems from vessel wall inflammation, prompting the use of immunosuppressive agents to address inflammation. While the 2018 revised European League Against Rheumatism (EULAR) guidelines don't routinely recommend anticoagulant (AC) therapy for vascular involvement, clinicians frequently include it in treatment plans. However, our study indicates that adding AC therapy to immunosuppressive (IS) treatment might not prevent new vascular attacks.

In our study, although IS treatment was promptly initiated upon detecting vascular involvement, its use during subsequent vascular attacks was low (21% and 7% in first and second relapses, respectively). This contrasts with higher IS usage rates reported by Alibaz et al. (50-60%) [18]. This discrepancy suggests that IS treatment duration may influence relapse occurrence. Factors such as side effects and patient non-compliance could contribute to early IS therapy discontinuation. Hence, guidelines for IS treatment duration in Behçet's disease with cardiovascular involvement may require revision for clearer recommendations.

Limitation

Our study's retrospective design poses limitations inherent to this approach, potentially introducing biases. Exclusion of patients with incomplete records may affect data accuracy. The relatively small sample size could limit the result's generalizability. Variability in assessing vascular involvement severity, differing follow-up durations, and short follow-up periods for some patients are additional limitations. Inadequate monitoring of the International Normalized Ratio (INR) in patients on anticoagulant therapy is another constraint, impacting accurate dosage determination. These limitations underscore the need for cautious interpretation and highlight the importance of future research with larger, standardized datasets.

Conclusion

Early detection and timely treatment initiation are pivotal in managing cardiovascular system (CVS) involvement in Behçet's disease to enhance patient outcomes. Our study underscores the significance of immunosuppressive therapy as the mainstay treatment approach for CVS involvement in Behçet's disease. Additionally, our findings indicate that the utilization of anticoagulants, either alone or combined with immunosuppressive therapy, does not offer protective benefits against vascular attack development.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or compareable ethical standards.

Funding: *None*

Conflict of Interest

The authors declare that there is no conflict of interest.

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How to cite this article:
Nurcin Ogreten Yadigaroglu, Refik Ali Sari, Sukriye Tasci, Metin Yadigaroglu. Evaluation of clinical features and treatment responses in cardiac and vascular involvement of Behçet's disease. Ann Clin Anal Med 2024;15(8):575-580

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